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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,567	11/14/2003	Paul Wentworth	1361.028US1	1768

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,567	WENTWORTH ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 27, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *21-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *October 27, 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

Throughout the specification, reference to the conversion of "singlet oxygen" into "reactive oxygen species" appears repugnant to the art-recognized definition of "reactive oxygen species" because persons skilled in the art generally do not recognize "singlet oxygen" as a separate genus, but rather recognize that "singlet oxygen" belongs to the broader genus of "reactive oxygen species."

On page 23, lines 6-7, the sentence beginning "Upon oxidation such chemical probes..." is indefinite because it is not clear whether said chemical probes are oxidized, or whether said chemical probes are oxidizing agents, and is thereby reduced.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 11, the claim preamble does not appear to correspond with the method outcome. For example, the preamble of claim 1 recites "a method for assaying for an immunological response" while step c recites the step of "analyzing the sample for an oxidized chemical probe." It is not clear how merely "analyzing the sample for an oxidized chemical probe" amounts to "a method for assaying for an immunological response."

In claims 1 and 11, the recitation of the infinitive "to [thereby] detect" is indefinite. Whether the act or process of detection is completed or performed, or merely intended, is not clear. The object(s) and/or step(s), if any, required for performing detection is/are not clear.

In claims 1 and 11, the recitation of "the inflammatory response" lacks antecedent basis.

Claim Rejections - 35 USC § 102

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Medford et al. (US 5,846,959).

Medford et al. describe a method for assaying for an immunological response (see col. 4, lines 48-54, "in vivo models of... inflammatory diseases... can be provided") in a mammal (see col. 4, lines 48-54, "host animal") comprising the steps of: administering a chemical probe for reactive oxygen (see col. 4, lines 36-39, "administration of an appropriate antioxidant", see col. 4, lines 48-54, "administering to a host animal an excessive amount of PUFA or oxidized polyunsaturated fatty acid"), obtaining a sample from the mammal (see col. 4, lines 28-35, "tissue or blood"), and analyzing the sample for an oxidized chemical probe (see col. 4, lines 28-35, "the level of oxidized polyunsaturated fatty acid, or other appropriate markers... is evaluated").

With respect to the limitation of a chemical probe "for" reactive oxygen species comprise oxygen with one or more unpaired electrons", Examiner observes that Medford et al. describe several chemical probes (see col. 4, lines 36-39, "antioxidant", see col. 4, lines 48-54, "PUFA or oxidized polyunsaturated fatty acid"; see Example 14, "cholesterol"). Absent object evidence presented to this Office to the contrary, Examiner posits that said chemical probes are inherently "for" oxygen with one or more unpaired electrons, and would be so recognized by persons of ordinary skill.

With respect to claims 2-3 and 12-13, Medford et al. describe a method comprising cholesterol (see Example 14).

With respect to claims 4-6 and 14-16, Medford et al. describe several chemical probes (see col. 4, lines 36-39, "antioxidant", see col. 4, lines 48-54, "PUFA or oxidized polyunsaturated fatty acid"; see Example 14, "cholesterol"). Absent object evidence presented to this Office to the contrary, Examiner posits that said chemical probes are inherently "for" antibody-generated oxygen species (claim 4), superoxide

radical, hydroxyl radical, peroxyl radical or hydrogen peroxide (claim 5), and ozone (claim 6), and would be so recognized by persons of ordinary skill.

With respect to claims 9 and 19, Medford et al. describe a tissue sample (see Example 14).

With respect to claims 10 and 20, Medford et al. describe UV spectrophotometry detection (see Example 16).

Response to Arguments

In prior Office Action, the drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because Figs. 19 and 20B did not include the reference sign "isatin sulfonic acid 2" as mentioned in the description on page 87-88. Applicants' amendment to the drawings filed October 27, 2005, is sufficient to overcome this objection. Accordingly, this objection is withdrawn.

In prior Office Action, claims 1-20 were rejected under 35 U.S.C. 102(b) as being anticipated by Medford et al. (US 5,846,959). In response, Applicants attempt to distinguish their invention from the teachings of Medford et al. by asserting that Medford et al. do not teach a step of detecting an immunological or inflammatory response, while Applicants' invention requires such a step of "detecting" an immunological or inflammatory response".

Examiner respectfully disagrees with Applicants' position premised on the assumption that Applicants' invention definitively recites a step of "detecting" an immunological or inflammatory response. Applicants' invention, as claimed, does not appear to require a detection step. Examiner posits that Applicants' invention, as claimed, reciting the infinitive "to [thereby] detect" is indefinite for the reasons set forth, *supra*, *Claim Rejections - 35 USC § 112*, and may not amount to the definitive creation of a detection step.

However, even if Applicants were to definitively recite a step of "detecting" an immunological or inflammatory response, Medford et al. nevertheless teach such a "detecting" step (see col. 4, lines 48-54, "in vivo models of... inflammatory diseases... can be provided"). Even if Applicants were to definitively recite a "detecting" step, Examiner need not invoke the Doctrine of Inherency to teach such a "detecting" step because Medford et al. explicitly teach the step.

Conclusion

No claims are allowed at this time.

In the interest of furthering future prosecution of the instant application, the following prior art reference is made of record, but not relied upon in the instant Office Action:

> Palozza & Krinsky, 213 METHODS ENZYMOL. 403 (1992), are cited for their teaching of a method for assaying for an immunological response in a mammal (see p. 403, last paragraph, "human disease") comprising the steps of: administering a chemical probe for reactive oxygen (see p. 417, fourth full paragraph, "carotenoids have been either injected or administered orally"), obtaining a sample from the mammal (see p. 418, Table IV, "Target"), and analyzing the sample for an oxidized chemical probe (see p. 410, Table II, "Product").

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner

LONG V. LE
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01/10/05